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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,882	01/13/2004	Toshio Miyata	SHIM-011DIV	3594

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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,882	MIYATA, TOSHIO	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 13, 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 22-25, 28-36, drawn to polynucleotides, vectors comprising the polynucleotides, host cells and a method of making polypeptides, classified in class 435, subclass 7.21; class 435, subclass 325; class 536, subclass 23.5; class 435, subclass 320.1, for example.

   II. Claims 26-27, drawn to an antisense oligonucleotide of SEQ ID NO:1, classified in class 536, subclass 24.5, for example.

   III. Claims 37-39, 41, drawn to an antibody against SEQ ID NO:2, classified in class 424, subclass 130.1, for example.

   IV. Claim 40, drawn to an immunoassay method, classified in class 435, subclass 7.1, for example.

   V. Claim 42, drawn to a method for detecting mesangial proliferative nephropathy, classified in class 435, subclass 7.1, for example.

   VI. Claims 43-45, drawn to a transgenic non-human vertebrate, classified in class 800, subclass 8, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of

operation, function, or effect. See MPEP § 806.05(j). In the instant case, the composition, structures and function of antisense oligos in the Group II are different from those in the Group I. Thus, Inventions I and II are patentably distinct.

3. Inventions IV and V are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806. 05(j). In the instant case, the method of detecting mesangial proliferative nephropathy could use antibodies to detect the protein of SEQ ID NO:2, or molecular biological methods such as in situ hybridization/Northern blot, or RT-PCR. The method of Group IV is not necessarily required by the method of Group V. In addition, patients in the Group V are not required by the Group IV. Thus, Inventions IV and V are patentably distinct.

4. Inventions III and IV, Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the antibodies against SEQ ID NO:2 (Group IV or Group V) can be practiced with alternative antibodies or other molecules. In addition, the products as claimed (Group III) can be used alternatively in a method of treatment, or a method of

screening compounds/detecting compositions. Thus, Inventions III and IV, Inventions III and V are patentably distinct

5. Inventions I-II and III, Inventions I-II and IV, Inventions I-II and V, Inventions I-II and VI, Inventions V and VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806:04, MPEP § 808.01). In this instant case, the products in the Group III are distinct from those in the Groups I-II as the products are comprised of divergent structure, effects and function. An antibody is composed of a pair of heavy chain and light chain of peptides, Fab fragments, for antigen-binding, and a pair of complement binding domain (Fc fragment). The use for antibody is various, for example the antibody can be used to detect a protein and also for immunotherapy as a therapeutical agent. Although the DNA can be used as a therapeutical agent, the effects of gene therapy are very different from those of antibodies because the mode of action and potential adverse effects of antibodies are different from gene therapy. Thus, Inventions I-II and III are patentably distinct. In addition, the products in the Groups I-II are not required by Groups IV and V. The procedures, materials and equipments used in the method of detecting mesangial proliferative nephropathy (Group V) are very different from those in an immunoassay and are not required by Group VI. Further, the patient populations are not required by the rest of Groups. The transgenic animal (Group VI) are not required by the rest of

III, Inventions I-II and IV, Inventions I-II and V, Inventions I-II and VI, Inventions V and VI are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VI as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

10. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
September 5, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER